

FILED

IN THE FIFTH CIRCUIT COURT OF DAVIDSON COUNTY, TENNESSEE 49

2013 MAY 15 PM 4:12  
RICHARD N. BOOKER, CLERK

WAYNE A. REED, individually and as  
Husband and next of kin of decedent,  
DIANA E. REED,

Plaintiff,

v.

SAINT THOMAS OUTPATIENT  
NEUROSURGICAL CENTER, LLC,  
HOWELL ALLEN CLINIC, a Professional  
Corporation, SAINT THOMAS NETWORK,  
SAINT THOMAS HEALTH, and ST.  
THOMAS HOSPITAL,

Defendants.

NO. 13C417

NOTICE OF FILING

Come now the Defendants, St. Thomas Outpatient Neurosurgical Center, LLC ("STOPNC") and Howell Allen Clinic, a Professional Corporation (hereinafter the "Defendants"), and hereby give notice to the parties and the Court of the filing of:

- (1) The unredacted (except for financial information) 2007 contract between STOPNC<sup>1</sup> and Michael O'Neal (hereinafter "Mr. O'Neal"), its pharmacist consultant
- (2) The unredacted (except for financial information) 2012 contract between STOPNC<sup>2</sup> and Michael O'Neal, its pharmacist consultant.

The Defendants file the contracts in further support of their Response to the Plaintiff's Motion to Compel and further evidence that:

1. Since 2007, Mr. O'Neal, as pharmacist consultant, functioned for STOPNC as a "quality improvement committee," as defined and contemplated by Tennessee Code Annotated § 68-11-272(b)(4)<sup>3</sup>.

<sup>1</sup> Incorrectly named as St. Thomas Neurosurgical Associates.

<sup>2</sup> Incorrectly named as St. Thomas NeuroSurgery Center.

2. Since 2007, Mr. O'Neal, as pharmacist consultant, functioned for STOPNC to evaluate the safety, quality, processes, and appropriateness of healthcare services by performing functions like those set out in Tennessee Code Annotated § 68-11-272(b)(4)(A)-(P).
3. Mr. O'Neal, in providing his services to STOPNC as set out in the contracts, was providing those services to STOPNC staff, and the STOPNC staff were functioning as "quality improvement committee(s)," as defined and contemplated by Tennessee Code Annotated § 68-11-272(4), in receiving that information to assist in evaluating the safety, quality, processes, and appropriateness of healthcare services at STOPNC.

The contracts and affidavit testimony in the record more than sufficiently establish that Mr. O'Neal and STOPNC participated continuously since 2007 in a "quality improvement" relationship and process. Both sides functioned as "quality improvement committees" as contemplated and defined by the statute, in furtherance of the policy set out in Tennessee Code Annotated § 68-11-272(a).

As such, any "records" or communications stemming from this relationship are privileged from discovery, inadmissible at trial, and outside the bounds of Rule 26 as not reasonably calculated to lead to the discovery of admissible evidence.

Mr. O'Neal provided the following functions, specifically enumerated in the contract, which are consistent with the specifically enumerated quality improvement functions explicitly protected by the statute:

---

<sup>3</sup> And Tennessee Code Annotated § 63-1-150, which sets out the same protections for "healthcare organizations" as defined in that section.

**2007 Contract**

<b>Quality Improvement Function in Contract(s)</b>	<b>Quality Improvement Function in Statute</b>
Consultation regarding "all laws, rules and regulations" related to medication use	(O) Activities to determine the healthcare organization's compliance with state or federal regulations
"Consult on all medication related matters"	(K) Evaluation of the quantity, quality and timeliness of healthcare services rendered to patients
"Assist the center in maintaining its accreditation status by all of its governing bodies"	(O) Activities to determine the healthcare organization's compliance with state or federal regulations
"Develop and aid in maintaining policies and procedures pertaining to any medication bought by or administered at the Surgery Center"	(L) Evaluation, review or improvement of methods, procedures or treatments being utilized
"Assist in making known to the staff recommended necessary exchanges of policies for better compliance with existing state and federal regulations as well as those of the center's accrediting bodies"	(I) Supervision, <i>education</i> , discipline, admission, and determination of privileges of <i>healthcare providers</i>  (L) Evaluation, review or improvement of methods, procedures or treatments being utilized  (O) Activities to determine the healthcare organization's compliance with state or federal regulations
"Teach staff to check stock medications for outdated medications before they are administered as well as proper rotation of stock"	(I) Supervision, <i>education</i> , discipline, admission, and determination of privileges of <i>healthcare providers</i>
"To routinely check all procedures and counts regarding controlled and non-controlled medications ordered and administered on the premises by staff"	(L) Evaluation, review or improvement of methods, procedures or treatments being utilized
"To establish record-keeping procedures, forms and documents necessary to meet existing accreditation body, state and federal regulations concerning such [sic]"	(L) Evaluation, review or improvement of methods, procedures or treatments being utilized  (O) Activities to determine the healthcare organization's compliance with state or federal regulations
"To assess the facility at each visit and to perform a monthly unit-check of all areas where medications are administered"	(A) Evaluation and improvement of the quality of healthcare services rendered  (H) Evaluation of whether facilities are being properly utilized
"To perform a bi-annual narcotic inventory of the narcotics stored in the facility and submit in writing this list for record-keeping within the facility"	(I) <i>Supervision</i> , education, discipline, admission, and determination of privileges of <i>healthcare providers</i>
"To assure proper documentation and record-keeping between the Pharmacy records and the patient's medical record"	(L) Evaluation, review or improvement of methods, procedures or treatments being utilized

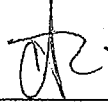
**2012 Contract**

<b>Quality Improvement Function in Contract(s)</b>	<b>Quality Improvement Function in Statute</b>
"Maintain current Pharmacy Registration in the State of Tennessee"	(O) Activities to determine the healthcare organization's compliance with state or federal regulations
"Consultant Pharmacist will visit the facility no less than every thirty five days to perform a routine inspection of all medication storage areas"	(H) Evaluation of whether facilities are being properly utilized
"To represent the Surgery Center, if requested, in on-site inspections from the State, Regulatory Agency and/or Accreditation Association, Board of Pharmacy, or Drug Enforcement Agency (DEA) in all matters related to medications is possible"	(O) Activities to determine the healthcare organization's compliance with state or federal regulations
"Direct and serve as a resource person to the Surgery Center's employees and physicians regarding the actions, interactions, compatibility, dosage, indications, and possible adverse reactions of pharmaceutical products utilized by the Surgery Center. Provide appropriate in-service training as necessary"	(A) Evaluation and improvement of the quality of healthcare services rendered  (I) Supervision, <i>education</i> , discipline, admission, and determination of privileges of <i>healthcare providers</i>
"To provide assistance to the Surgery Center in developing and evaluating, on an annual basis, appropriate policies and procedures for the safe and effective use of drugs within the facility. To also assure that policies and procedures also address State and Federal regulatory and compliance issues of drug procurement, selection, storage, distribution, use, destruction, documentation, monitoring, and record keeping as required"	(L) Evaluation, review or improvement of methods, procedures or treatments being utilized  (O) Activities to determine the healthcare organization's compliance with state or federal regulations
"Work closely with the Surgery Center's designated medication nurse to establish sufficient par levels for each designated area"	(A) Evaluation and improvement of the quality of healthcare services rendered  (I) Supervision, <i>education</i> , discipline, admission, and determination of privileges of <i>healthcare providers</i>
"Supervise inventory controls for narcotics and all other drugs (orders and charts within DEA guidelines)"	(I) Supervision, <i>education</i> , discipline, admission, and determination of privileges of healthcare providers  (L) Evaluation, review or improvement of methods, procedures or treatments being utilized  (O) Activities to determine the healthcare organization's compliance with state or federal regulations
"To reasonably respond to telephone requests for technical information and procedural questions, etc. requested by center management or clinical drug information for members of the nursing and medical staffs"	(I) Supervision, <i>education</i> , discipline, admission, and determination of privileges of <i>healthcare providers</i>

"Assist in the development for Quality Improvement Process regarding medication management related procedures and attends and participates in the quarterly Quality Improvement Process meetings when applicable and available"	(A) Evaluation and improvement of the quality of healthcare services rendered  (D) Evaluation of the qualifications, credentials, competence and performance of healthcare providers  (I) <i>Supervision, education</i> , discipline, admission, and determination of privileges of <i>healthcare providers</i>  (J) Review of professional qualifications or activities of healthcare providers  (L) Evaluation, review or improvement of methods, <i>procedures or treatments</i> being utilized
"Assist in the establishment and maintenance Surgery Center medication formulary in conjunction with the Medical Executive Committee and the facility's designated medication nurse"	(I) <i>Supervision, education</i> , discipline, admission, and determination of privileges of healthcare providers  (L) Evaluation, review or improvement of methods, <i>procedures or treatments</i> being utilized
"Assist center staff in monitoring for expired medications and proper storage of all medications"	(E) Reduction of morbidity or mortality
"Oversee that proper procedure is carried out in the destruction or return of outdated or unused drugs following all DEA guidelines"	(E) Reduction of morbidity or mortality  (O) Activities to determine the healthcare organization's compliance with state or federal regulations
"Oversee the surgery center's medication distribution system"	(I) <i>Supervision</i> , education, discipline, admission, and determination of privileges of healthcare providers
"Oversee all required records and conducts audit checks of controlled substances perpetual inventory"	(H) Evaluation of whether facilities are being properly utilized  (L) Evaluation, review or improvement of methods, <i>procedures or treatments</i> being utilized
"Will assist in the renewal and obtaining of all state and federal registrations"	(O) Activities to determine the healthcare organization's compliance with state or federal regulations
"Oversee all IV admixture usage"	(L) Evaluation, review or improvement of methods, <i>procedures or treatments</i> being utilized

Respectfully submitted,

**GIDEON, COOPER & ESSARY, PLC**



C.J. Gideon, Jr., #6034

Chris J. Tardio, #23924

Matt Cline, #31076

Suite 1100

315 Deaderick Street

Nashville, TN 37238

(615) 254-0400

*Attorneys for Defendants  
Howell Allen and STOPNC*

**CERTIFICATE OF SERVICE**

I hereby certify that a true and correct copy of the foregoing was served on the following via email on this 15<sup>th</sup> day of May, 2013:

William D. Leader, #9531  
George H. Nolan, # 14974  
Leader, Bulso & Nolan  
414 Union Street, Suite 1740  
Nashville, TN 37219

*Attorneys for Plaintiff*

William H. Lassiter, Jr.  
John Overton Belcher  
Lassiter Tidwell & Davis  
150 4<sup>th</sup> Avenue North, Ste. 1850  
Nashville, TN 37219

*Attorneys for Plaintiff*

Lela M. Hollabaugh, # 14894  
Amy D. Hampton, # 22826  
Bradley Arant Boult Cummings, LLP  
1600 Division Street, Suite 700  
Nashville, TN 37203

*Attorneys for Defendant St. Thomas  
Hospital*

Mary M. Bers, #13159  
Joseph Ahillen, #028378  
Office of the Attorney General  
PO Box 20207  
Nashville, TN 37202-0207

*Attorneys for State of Tennessee*



**Chris J. Tardio**



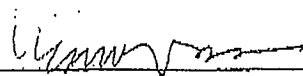
## Pharmacy Consulting Contract Michael D. O'Neal

This agreement, entered into on February 1, 2007, between the St Thomas Neurosurgical Associates and Michael David O'Neal, a duly licensed pharmacist in the State of Tennessee, for the purpose of providing an available pharmacy license for the Oral Surgical Institute licensure by the Tennessee Department of Health and to act as a consultant to the said facility as to be stated below.

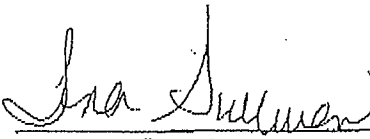
Pharmacy Consultant will perform the following duties:

- All duties concerning consultation to all laws, rules and regulations and the administration of such at the Surgery Center
- Consult on all medication related matters
- Assist the center in maintaining its accreditation status by all of its governing bodies
- Develop and aid in maintaining policies and procedures pertaining to any medication bought by or administered at the Surgery Center
- Assist in making known to the staff recommended necessary exchanges of policies for better compliance with existing state and federal regulations as well as those of the center's accrediting bodies
- Teach staff to check stock medications for outdated medications before they are administered as well as proper rotation of stock
- To routinely check all procedures and counts regarding controlled and non-controlled medications ordered and administered on the premises by staff
- To establish record-keeping procedures, forms and documents necessary to meet existing accreditation body, state and federal regulations concerning such
- To assess the facility at each visit and to perform a monthly unit-check of all areas where medications are administered
- To perform a bi-annual narcotic inventory of the narcotics stored in the facility and submit in writing this list for record-keeping within the facility
- To assure proper documentation and record-keeping between the Pharmacy records and the patient's medical record

Fees for consultation service are as follows: A one-time fee of \$1000 will be collected at the time this contract is signed by both parties. On all proceeding months, \$1000 will be paid by the facility on the 1<sup>st</sup> of every month beginning February, 2007, when this contract shall take effect. This contract may be terminated by either party without cause upon the written submission of a 30 day notice.

  
Pharmacist

3/20/07  
Date

  
Facility Administrator

3/20/07  
Date

- K. Assist in the establishment and maintenance Surgery Center medication formulary in conjunction with the Medical Executive Committee and the facility's designated medication nurse.
- L. Assist center staff in monitoring for expired medications and proper storage of all medications.
- M. Oversee that proper procedure is carried out in the destruction or return of outdated or unused drugs following all DEA guidelines.
- N. Oversee the surgery center's medication distribution system.
- O. Oversee all required records and conducts audit checks of controlled substances perpetual inventory.
- P. Will assist in the renewal and obtaining of all state and federal registrations.
- Q. Oversee all IV admixture usage.

The Consultant agrees that any information received by the Consultant during any furtherance of the Consultant's obligations in accordance with this Agreement, which concerns the business, personal, financial, or other affairs of the ASC will be treated by the Consultant in full confidence and will not be revealed to any other person, firms or organization. The ASC shall be responsible to the consultant for providing the necessary information to assist in compliance with standards and policies. The ASC's failure to provide such information, including documentation and other necessary resources, shall relieve the consultant of any responsibility to assist in compliance with standards and policies.

3. Place Where Services Will Be Rendered.

The Consultant will perform most services in accordance with this Agreement at:

St Thomas NeuroSurgery Center  
4230 Harding Road  
Suite 901  
Nashville, Tennessee 37205

4. Compensation.

Consultant will be compensated by ASC for professional activities related to provision of pharmaceutical consulting services provided to its Surgery Center in Nashville, Tennessee, according to the fee schedule described in Exhibit "A".

5. Extent of Service.

The Consultant shall devote adequate time to the services as shall be reasonably necessary to adequately fulfill its duties hereunder. It is, however, understood and agreed that the Consultant is an independent contractor and not an employee of the Surgery Center. Accordingly, the Consultant shall be responsible for payment of all taxes including Federal, State, and local taxes arising out of the Consultant's activities in accordance with this Agreement.

6. Records And Inspection

Each party hereto agrees to make available to the other party such records and information as may be necessary in order to determine payments due under this Agreement; provided, however, that all information shall be subject to all federal, state, and local requirements regarding confidentiality of medical records.



7. Confidentiality.

Unless otherwise required by law, both parties hereto agree to keep confidential this Agreement and not to disclose terms and conditions of this Agreement to third parties without prior written consent.

8. Relationship Between Parties.

It is mutually agreed that nothing herein shall be construed to create the relationship of agent, employee, partnership, joint venture, and employer and that Consultant is and shall be deemed to be an independent contractor. Consultant shall not have authority to take any actions on the ASC's behalf nor shall the ASC be bound in any manner to any action undertaken or any statement made by Consultant unless it has consented in advance in writing to such actions or statements. Consultant shall not be considered under the provisions of this Agreement or otherwise as having an employee status.

9. Insurance

Consultant, at her sole cost and expense, shall maintain policies of professional liability insurance, including malpractice coverage in the amount of [REDACTED] for each claim and [REDACTED] for aggregate claims for on occurrence. Such insurance policies shall be obtained from a reputable company authorized to sell liability insurance in the State of Tennessee.

10. HIPAA Requirements

Provider agrees to comply with the Health Insurance Portability and Accountability Act of 1996, as codified at 42 U.S.C. § 1320d ("HIPAA") and any current and future regulations promulgated there under including without limitation the federal privacy regulations contained in 45 C.F.R. Parts 160 and 164 (the "Federal Privacy Regulations"), the federal security standards contained in 45 C.F.R. Part 142 (the "Federal Security Regulations"), and the federal standards for electronic transactions contained in 45 C.F.R. Parts 160 and 162, all collectively referred to herein as "HIPAA Requirements". Provider agrees not to use or further disclose any Protected Health Information (as defined in 45 C.F.R. Section 164.501) or Individually Identifiable Health Information (as defined in 42 U.S.C. Section 1320d), other than as permitted by HIPAA Requirements and the terms of this Agreement.

Provider will make its internal practices, books, and records relating to the use and disclosure of Protected Health Information available to the Secretary of Health and Human Services to the extent required for determining compliance with the Federal Privacy Regulations. The ASC should provide for methods to insure compliance with HIPAA requirements and shall defend, indemnify and hold harmless consultant in connection with said requirements.

11. General Provisions

Severability. If any term, provision, covenant, or condition of this agreement is held by a court of competent jurisdiction to be invalid, void, or unenforceable, the remainder of the provisions herein shall remain in full force and effect and shall in no way be affected, impaired, or invalidated as a result of such decision.

Notice. Any notice required or permitted to be given pursuant to this agreement shall

be in writing and either shall be delivered personally or sent by certified mail with the United States Postal Services, return receipt requested, postage prepaid, or express mail addressed to the following:

If to Consultant:

Michael D. O'Neal  
PO Box 128562  
Nashville, TN 37212

If to ASC:

Debra Schamberg, Administrator  
o/o St Thomas NeuroSurgery Center  
4230 Harding Road  
Suite 901  
Nashville, TN 37205

If sent by registered mail, return receipt requested or express mail, such notice shall have been deemed to have been delivered to the party to whom it was addressed on the third business day after the day on which it was mailed to such party at such address.

Modification. It is expressly agreed by both parties that the terms of this Agreement and the Exhibit which has been incorporated herein comprise the entire Agreement between parties and no other agreement or understanding, oral, or otherwise, exists between the parties at the time of execution hereof. This Agreement shall not be subject to rescission, modification, or waiver except as defined in a subsequent written instrument executed by both parties hereto.

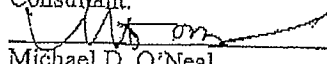
Assignability. This Agreement or any duty or obligation of performance hereunder may not be assigned, in whole or in part, by either party without prior written consent of the other party subject to the foregoing, this Agreement shall be binding upon and inure to the benefit of the parties and their respective heirs, representatives, successors, and permitted assigns.

Waiver. The waiver by either party of one or more defaults on the part of the other shall not be construed to operate as a waiver of any subsequent default.

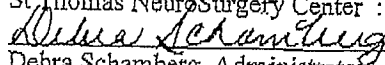
Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed to be an original, but all of which together shall constitute one and the same Agreement.

IN WITNESS WHEREOF, the parties have executed this Agreement on the 1<sup>st</sup> of September 2012.

Consultant:

  
Michael D. O'Neal  
Registered Pharmacist

4/4/12  
Date

St Thomas NeuroSurgery Center :  
  
Debra Schamberg, Administrator

9-7-12  
Date

EXHIBIT "A"

SCHEDULE OF FEES

ONGOING CONSULTANT SERVICES FOR THE CONTRACT PERIOD

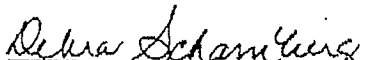
---

The Consultant Pharmacist shall provide ongoing consulting services as outlined in #3 above to assist in carrying out the center's pharmaceutical policies and procedures and maintain compliance with applicable Federal, State, and Local laws. The monthly fee for ongoing consulting pharmaceutical services is ~~XXXX~~ made payable to 'Michael D. O'Neal'. This fee is to be paid within 15 days following the end of the month in which the services were provided. This contract shall be executed September 1, 2012 and carry forward thereto.

The execution of this Agreement indicates the acceptance by the undersigned parties to their respective responsibilities. All payment for services rendered shall be due 15 days from the statement date.


The full cooperation of the executive, administrative, and professional staffs of the St Thomas NeuroSurgery Center in assisting in *implementing* policies and procedures as recommended by the consultant or as required by Stature shall *be assured*. *The ASC shall defend, indemnify and hold harmless consultant from any and all claims arising out of this agreement.*

St Thomas NeuroSurgery Center:

  
Debra Schamberg, Administrator  
Administrator

9-7-12  
Date

CONSULTANT:

  
Michael D. O'Neal  
Registered Pharmacist

9/4/13  
Date